



**ENZYMATIC THERAPY**  
INCORPORATED  
*What **Better** feels like.™*

**INTEGRATIVE THERAPEUTICS INC.™**  
NF Formulas • PhytoPharmica  
Tyler Encapsulations • Vitaline Formulas

9755 SW Commerce Circle, Suite B2  
Wilsonville, OR 97070  
P: 503.582.8386 • F: 503.582.0467

**ENZYMATIC THERAPY™**  
&  
**PHYTOPHARMICA™**

825 Challenger Drive, Green Bay, WI 54311-8328  
P: 920.469.1313 • F: 888.570.6460 (Enzymatic)  
P: 920.469.9099 • F: 920.469.4418 (Phyto)

0826 5 MAY -2 P3:09

April 11, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.



PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Protective Breast Formula™*	Protective Breast Formula contains effective dosages of seven key ingredients that provide the protection benefits found in certain foods.*	Vitamin D (as cholecalciferol), Calcium (as calcium D-glucarate), Turmeric (Curcuma longa) Rhizome Extract, Calcium d-Glucarate, Green Tea (Camellia sinensis) Leaf Extract, Indoplex Complex, Grape (Vitis vinifera) Seed Extract, Maitake (Frifola frondosa) Mushroom Extract

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiated that the statements are truthful and not misleading.

*Robert*

By: \_\_\_\_\_  
Robert Doster  
Title: Senior Vice President of Scientific Affairs

Date: 4-11-05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,  
*Michael P. Devereux*  
Michael P. Devereux  
Chief Financial Officer

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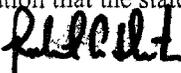
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Protective Breast Formula™*	This nutrient powerhouse defense is a vital foundation for breast health.*	Vitamin D (as cholecalciferol), Calcium (as calcium D-glucarate), Turmeric (Curcuma longa) Rhizome Extract, Calcium d-Glucarate, Green Tea (Camellia sinensis) Leaf Extract, Indolplex Complex, Grape (Vitis vinifera) Seed Extract, Maitake (Fritola frondosa) Mushroom Extract

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By: 

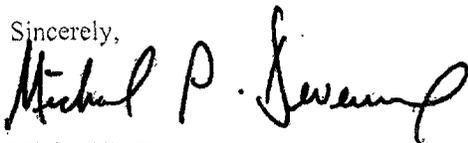
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 4-11-05

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Michael P. Devereux  
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April 12, 2005

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Protective Breast Formula™*	Supplementing with Protective Breast Formula and incorporating simple lifestyle changes will help in attaining optimum health.*	Vitamin D (as cholecalciferol), Calcium (as calcium D-glucarate), Turmeric (Curcuma longa) Rhizome Extract, Calcium d-Glucarate, Green Tea (Camellia sinensis) Leaf Extract, Indoplex Complex, Grape (Vitis vinifera) Seed Extract, Maitake (Frifola frondosa) Mushroom Extract

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